IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE PLAVIX® PRODUCT LIABILITY AND MARKETING LITIGATION

Docket No. 13-cv-02418-FLW-TJB

PAUL DARRAH,
Plaintiff,
vs.
BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., and SANOFI-SYNTHELABO INC.,
Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW, Plaintiff, Paul Darrah, who brings this action against Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo Inc. (collectively, "Sanofi"), for injuries and damages suffered as a result of ingesting the drug, Plavix. In support, Plaintiff alleges the following.

PARTIES

1. Plaintiff, Paul Darrah, is a natural person currently residing, and at all times material to this complaint, at #2012016837, The Andrew C. Baird Detention Facility, 570 Clinton St., Detroit, MI 48226. Plaintiff brings this Complaint on his own behalf, and through undersigned counsel, against BMS and Sanofi, the manufacturers and marketers of Plavix, for injuries sustained from the drug.

2. Defendant, Bristol-Myers Squibb Company, is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-

Aventis U.S., Inc.) to manufacture and market Plavix in the United States. The headquarters for Bristol-Myers Squibb Company is located at 345 Park Avenue in New York, New York, 10145-0037.

3. Defendant, Sanofi-Aventis U.S. L.L.C., is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A Bridgewater, New Jersey 08807-0912.

4. Defendant, Sanofi-Aventis U.S., Inc., formerly known as Sanofi-Aventis U.S. Inc., is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.

5. Defendant, Sanofi-Synthelabo, Inc. is a Delaware corporation with its commercial headquarters at 90 Park Avenue in New York, New York 10016. Sanofi-Synthelabo Inc. did business as Sanofi Pharmaceuticals, Inc. and was the sponsor for the drug application for Plavix. Sanofi-Synthelabo, Inc. is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis, Inc. that was instrumental in bringing Plavix to market.

JURISDICTION AND VENUE

6. Jurisdiction and venue of this case is proper pursuant to Case Management Order No. 2 (ECF No. 91) whereby direct filing of a complaint into the MDL proceedings of the District of New Jersey is permitted.

STATEMENT OF FACTS

7. Plaintiff, Paul Darrah, was 41 years old when, on or about February 3, 2006, he was hospitalized and treated for gastrointestinal bleeding after ingesting Plavix.

8. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Plavix.

9. At all material times, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants.

10. Defendants misrepresented that Plavix is a safe and effective treatment for the prevention of heart attacks and strokes, when in fact the drug causes serious medical problems, including life threatening events such hemorrhagic bleeding.

11. The Sanofi Defendants and BMS co-developed Plavix, applying in April 1997, for a rare priority regulatory review, by the U.S. Food and Drug Administration (FDA), which cleared the way for Defendants to bring Plavix to market in November 1997.

12. The rush to obtain FDA approval of Plavix is indicative of Defendants' emphasis on marketing and profit making over patient safety.

13. Plavix was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.

14. The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin

to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering any hemorrhage carries with it the possibility of death, which far outweighs any potential benefit.

15. Still, BMS and Sanofi continued to exaggerate the results of their own studies and made false statements in their advertising and promotional materials for the purpose of increasing their profits from Plavix sales.

16. The profit at stake for Defendants is enormous. By way of illustration, in 2005, Plavix, was the sixth top selling drug in the United States and Defendants enjoy annual sales of Plavix totaling $3.8 Billion Dollars.

17. BMS and Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about the Plavix drug product they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promotional practices.

18. As examples, in 1998, the FDA requested Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were Defendants' marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA approved dosage nearly four (4) times that of other applications be given.

19. That same FDA warning criticized Defendants' attempts at over-promotion of Plavix for unapproved use for lacking fair balance and failing to disclose any of the risks associated with its use. In particular, the FDA criticized that Defendants were claiming to physicians, in their promotional letter, that Plavix was safe for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix. In particular, its safety when combined with

aspirin (known as "dual therapy") had not been established, yet Defendants were making a claim that the dual combination therapy of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance Trial), which was reported in The New England Journal of Medicine, April 20, 2006.

20. Again, in 1998, the FDA issued a letter demanding Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.

21. Undaunted, Defendants were back in the business of hiding bad facts about their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced to order Defendants to immediately cease distribution of promotional materials that made unsubstantiated and misleading claims about their Plavix drug product. Specifically, Defendants' promotional materials mislead consumers about their own study, called CAPRIE (Clopidogrel versus Aspirin in Patients at Rick of Ischemic Events). While Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin--providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

22. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives also misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.

23. From the outset, Defendants knew or should have known that a significant percentage of patients were genetically predisposed to have substantially diminished or no responsiveness to Plavix. Defendants were required by law to disclose this information to the FDA but failed to do so because it knew that disclosure would lead to a reduction in the number of prescriptions written for Plavix and, consequently, a decline in sales revenue.

24. By the end of 2006, it was clear to the scientific community that Plavix must be transformed into an active metabolite by CYP enzymes in order for it to have the desired anti-platelet effect, (ii) the CYPC19 enzyme plays an important role in metabolizing Plavix, (iii) the genes encoding the CYP enzymes are polymorphic, meaning that they contain multiple alleles, and (iv) common alleles of that CYP enzyme genes lead to reduced functionality, and thus diminished or no responsiveness to Plavix. However, there is no indication that Defendants brought this attention of the FDA, as was required by the FDCA and applicable regulations or to physicians to whom they were promoting the drug at that time.

25. Moreover, Defendants responded to the adverse efficacy data by proactively encouraging physicians to prescribe higher or double doses of Plavix to affected patients, telling them that higher doses would counteract the diminished functionality of the patient's CYP system enzymes. In other words, Defendants' improper conduct was thus not one of only omission but commission in that they told physicians that they were providing them with all pertinent facts for Plavix, even as they withheld the unfavorable data regarding the CYP2C19 gene.

26. Defendants knew that, if the FDA and medical community were fully informed that as much as 30% of the population was genetically predisposed to have diminished or no response to Plavix, then physicians would treat those patients using alternate therapies instead of Plavix. Despite having knowledge, Defendants did not include a "Black Box" warning, which would alert physicians to the drug's diminished effectiveness in poor metabolizers, until only recently.

27. Defendants, through their drug representatives and their promotional efforts, have encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone (without risking death) and to use Plavix for unapproved applications.

28. The result is that physicians are prescribing Plavix to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, but instead pay approximately four dollars ($4.00) a day for a single dose of Plavix.

29. Defendants' nearly eight-year run of lying to physicians and to the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal not only is Plavix not worth its high price—it is dangerous.

30. The Chan study, written about in The New England Journal of Medicine and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertion that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the

prescribing guidelines for Plavix be changed so that the patients would not erroneously believe that Plavix is safer on the stomach than aspirin.

31. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four-dollar ($4.00) a day Plavix pill that greatly increases the risk of stomach bleeding.

32. Most recently, the CHARISMA trial uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.

33. Despite the growing body of scientific knowledge that the four-dollar ($4.00) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.

34. The label for Plavix drug products, known as the “Package Insert” was developed by Defendants and accompanied all Plavix prescription drug products and/or samples and was published in the Physician’s Desk Reference.

35. Drug labeling is to include accurate information concerning a drug’s active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions, and side effects.

36. Defendants failed to fully, truthfully, and accurately communicate the safety and efficacy of Plavix drug products and intentionally and fraudulently mislead the medical community, physicians, Plaintiff's physicians, and Plaintiff about the risks associated with Plavix.

37. Defendants fraudulently and aggressively promoted Plavix drug products to physicians for use in patients, including Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures, leaflets and handouts as these materials downplayed the significance of the adverse effects of Plavix.

38. At all relevant times hereto, Defendants did not investigate the accuracy of the Plavix drug product labeling.

39. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of the true effects described above to the FDA, healthcare providers and patients, including Plaintiff.

40. Defendants were required to report literature, papers; and, to undertake action to reflect truthful and accurate information in its labeling and promotional materials and failed to do so.

41. Defendants are under a duty to ensure that their Plavix drug product labels are accurate.

42. Defendants failed to ensure its Plavix warnings to the medical community were accurate and adequate and breached this duty.

43. Defendants have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or

prevalence of side effects caused by Plavix drug products, the medical community, Plaintiff's physician, Plaintiff and other foreseeable users, and failed to fulfill this duty.

44. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Plavix, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their Plavix drug products.

45. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Plavix drug products to said persons and other foreseeable users.

46. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report significant data concerning the lack of efficacy and side effects associated with Plavix.

47. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in Plavix drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff, Plaintiff's physicians, and other foreseeable users.

48. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by Plavix drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians,

Plaintiff's physicians, Plaintiff, and other foreseeable users about the safety and efficacy of Plavix drug products.

49. At all times material hereto, Defendants knew or should have known that physicians and plaintiff were unaware of or did not fully appreciate the seriousness of the risks associated with use of Plavix drug products and the lack of benefit

50. At the time Defendants made the above-described representations, Plaintiff and Plaintiff's physicians, were ignorant of the falsity of the representations and reasonably believed them to be true.

51. Plaintiff's injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Plavix.

52. In doing the acts alleged in this Complaint, Defendants acted with oppression, fraud, and malice, and Plaintiff may therefore be entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future.

53. As a proximate result of the fraud and deceit of Defendants, Plaintiff sustained the injuries and damages as described in this Complaint.

54. Defendants have an absolute duty to disclose the true facts regarding the safety of Plavix drug products to the medical community, to physicians and their patients, which they negligently and/or intentionally failed to do.

55. Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of Plavix were accurate which it negligently and/or intentionally failed to do.

56. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Defendants.

57. Defendants' misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

58. A reasonably competent physician who prescribed Plavix and a reasonably competent Plaintiff who consumed Plavix would not realize its dangerous condition.

59. The reasonably foreseeable use of Plavix drug products involved substantial dangers not readily recognizable by Plaintiff's physicians, who acted as ordinary, reasonable and prudent physicians would, when prescribing Plavix to ordinary, reasonable and prudent patients, like Plaintiff.

60. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug, Plavix, is safe and free from serious side effects.

61. As a direct and proximate result of the aforesaid acts of and/or omissions by Defendants, Plaintiff has:

(a) Incurred and will continue to incur various sums of money for past, present, and future medical expenses associated with monitoring and treating Plaintiff's injuries; and

(b) Incurred attorney's fees and expenses of litigation related to this action.

62. Defendants' actions were intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences and acted only out of self-interest and personal gain and evidenced a specific intent to cause harm to Plaintiff.

63. Plaintiff's injuries came about as a foreseeable and proximate result of Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of Plavix to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of Plavix.

COUNT I
STRICT PRODUCTS LIABILITY

64. At all relevant times, Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling Plavix.

65. Plavix is defective and unreasonably dangerous to consumers.

66. At all times mentioned in this Complaint Plavix was defective and/or unreasonably dangerous to Plaintiff and other foreseeable users at the time it left the control of Defendants.

67. Plavix is defective in its design or formulation in that when it left the hands of Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.

68. The foreseeable risks associated with the design or formulation of Plavix, include, but are not limited to, the fact that the design or formulation of Plavix is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

69. At all times material to this action, Plavix was expected to reach, and did reach consumers throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

70. Defendants, developed, marketed and distributed Plavix drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of Plavix.

71. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that Plavix created a high risk of bodily injury and serious harm.

72. The dangerous propensities of Plavix drug products were known or scientifically knowable, through appropriate research and testing, to Defendants at the time said Defendants distributed, supplied, or sold Plavix, and not known to ordinary physicians who would be expected to prescribe Plavix for their patients.

73. Plavix drug products, as distributed, were defective and unreasonably dangerous in as much as Plavix was not accompanied by warnings and instructions that were appropriate and adequate to render Plavix reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of Plavix.

74. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of Plavix drug products with knowledge that consumers would be exposed to serious danger.

75. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to one or more of the particulars:

(a) At the time Plavix left the control of Defendants, Plavix was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because Plavix breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.

(b) Plavix drug products were not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time Plavix left the possession of Defendants, and that such risks clearly outweighed the

utility of Plavix therapy or its therapeutic benefits, and subjected Plaintiff to the risk of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users;

(c) At the time Plavix left the control of Defendants Plavix possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time Plavix left the possession of Defendants. Specifically, Defendants were well aware that Plavix products could potentially cause severe side effects.

(d) Defendants' warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of Plavix taking into account the characteristics of the Plavix, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases Plavix, such as Plaintiff.

(e) Plavix manufactured and supplied by Defendants was further defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risks of injury from Plavix drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and adequately warn about the risks of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and death associated with the use of Plavix.

(f) When placed in the stream of commerce of commerce, Plavix was defective in design and formulation, making the use of Plavix more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market including Aspirin

(g) Plavix was insufficiently tested.

76. Defendants knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery.

77. Defendants knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of Plavix that caused the damages for which Plaintiff seeks recovery.

78. The reasonably foreseeable use of Plavix involved substantial dangers not readily recognizable by the ordinary physician who prescribed Plavix or the patient, including Plaintiff, who consumed Plavix drug products.

79. Defendants knew that Plavix drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that Plavix were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

80. Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

81. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of Defendants' Plavix drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

82. The above defects caused serious injuries to Plaintiff when Plavix was used in its intended and foreseeable manner, and in the manner recommended by Defendants and/or in a non-intended manner that was reasonably foreseeable.

83. In addition, at the time that Plavix left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of Plavix. These safer designs were economically and technologically feasible and would have

prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.

84. As a direct and proximate result of the wrongful acts of Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

85. For the above reasons, Defendants are strictly liable under product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and/or punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT II
MANUFACTURING DEFECT

86. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Plavix.

87. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of Michigan and throughout the United States, including Plaintiff, without substantial change in the condition from which it was sold.

88. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a

defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury.

(a) When placed in the stream of commerce, Plavix contained manufacturing defects that rendered the product unreasonably dangerous;

(b) Plavix's manufacturing defects occurred while the product was in the possession and control of Defendants;

(c) Plavix was not made in accordance with Defendants' product specifications or performance standards; and

(d) Plavix's manufacturing defects existed before it left the control of Defendants.

89. As a direct and proximate result of the wrongful acts of Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

90. For the above reasons, Defendants are strictly liable under Michigan product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT III
FAILURE TO WARN

91. Plavix was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff and/or their health care providers, of the dangerous risks and reactions associated with Plavix, including but not limited to its propensity to cause avoidable strokes, heart attacks, abnormal bleeding, and other serious injuries and side effects despite Defendants' knowledge of the increased risk of these injuries over similar drugs such as aspirin.

92. Plavix was defective due to inadequate post-marketing warnings or instruction because after Defendants knew or should have known of the risk and danger of serious bodily harm and/or death from the use of Plavix, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

93. Plaintiff was prescribed and used Plavix for its intended purpose.

94. Plaintiff could not have known about the dangers and hazards presented by Plavix. The warnings that were given by Defendants were not accurate, clear, and complete and/or were ambiguous.

95. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of stroke, heart attack, bleeding and other serious injuries and side effects, and failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

96. The warnings that were given by Defendants failed to properly warn consumers of the increased risk of stroke, heart attack, bleeding, and other serious injuries and side effects.

97. Plaintiff, individually, and prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Plavix. Had Plaintiff received adequate warnings regarding the risks of Plavix, he would not have used Plavix.

98. As a direct and proximate result of Plavix's defective and inappropriate warnings, Plaintiff suffered severe physical injuries and damages as described above.

99. As a direct and proximate result of the wrongful acts of Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

100. For the above reasons, Defendants are strictly liable under Michigan product liability law without regard to proof of negligence or gross negligence.

WHEREFORE, Plaintiff demands judgment against suit, attorney's fees and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENCE

101. Defendants had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of Plavix to ensure the safety of Plavix and to ensure that the consuming public, including Plaintiff and Plaintiff's physicians and agents, obtained accurate information and instructions for the use of Plavix.

102. Defendants owed a duty toward foreseeable users of Plavix drug products to exercise reasonable care to ensure that Plavix drugs were reasonably safe for ordinary and intended uses, and specifically, inter alia, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks increased heart attack or stroke, blood disorders, excessive bleeding, and death described above.

103. Defendants failed to exercise reasonable care in testing Plavix for side effects in ordinary and foreseeable users; and failed to disseminate to physicians accurate and truthful information concerning the effects of Plavix; thus, physicians were not able to make informed choices concerning the use of Plavix drug products.

104. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of Plavix into the stream of commerce in that Defendants knew or should have known that Plavix drug products created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

105. The dangerous propensities of Plavix drug products as referenced above, were known or scientifically knowable, through appropriate research and testing, to Defendants at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe Plavix for Plaintiff and other patients, similarly situated.

106. The information Defendants disseminated to physicians concerning Plavix drug products was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

107. As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when he ingested Plavix.

108. Defendants was negligent, and breached their duties of reasonable care to Plaintiff with respect to Plavix drug products in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendants failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of Plavix;

(b) Defendants failed to conduct adequate testing; and

(c) Despite knowledge of hazards, Defendants failed to conduct adequate post-marketing surveillance to determine the safety of the product; and

(d) Despite knowledge of hazards, Defendants failed to adequately warn Plaintiff's physicians or Plaintiff that the use of Plavix drug products could result in severe side effects as described above;

(e) Despite the fact that Defendants knew or should have known that their Plavix drug products caused unreasonably dangerous side effects, Defendants failed to adequately disclose the known or knowable risks associated with Plavix as set forth above; Defendants willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety and/or welfare;

(f) Defendants failed to design, develop, implement, administer, supervise and monitor its clinical trials for Plavix;

(g) Defendants, in its promotion of Plavix, were overly aggressive and deceitful, and promoted Plavix in a fraudulent manner, despite evidence known to Defendants that Plavix was dangerous.

109. As a direct and proximate result of the wrongful acts of Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and has been otherwise damaged to be further shown by the evidence.

110. The negligence, carelessness, and the willful and wanton misconduct of Defendants was a proximate cause of Plaintiff's harms and injuries that Plaintiff suffered and will continue to suffer.

111. In the alternative, Defendants' acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing Plavix drug products.

112. Defendants concealed and suppressed the true facts concerning Plavix with the intent to deceive Plaintiff, in that Defendants knew that Plaintiff's physicians would not prescribe Plavix, and Plaintiff would not have taken Plavix, if they were aware of the true facts concerning its dangers.

113. Furthermore, the economic damages and physical harm caused by Defendants' conduct would not have occurred had Defendants exercised the high degree of care imposed upon it and Plaintiff therefore also pleads the doctrine of res ipsa loquitur.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

JURY DEMAND

Plaintiff demands a trial by jury.

PRAYER FOR RELIEF

For these reasons, Plaintiff requests that Defendants be cited to answer and appear, and that upon final trial, that Plaintiff receive a judgment against Defendants for Plaintiff's damages as set forth above, for attorneys' fees and expenses, for exemplary damages, for pre- and post-judgment

interest at the maximum rate allowed by law, for costs of court, and for such other and further relief to which Plaintiff may be justly entitled.

Respectfully Submitted,

By: /s/Barrett Beasley
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